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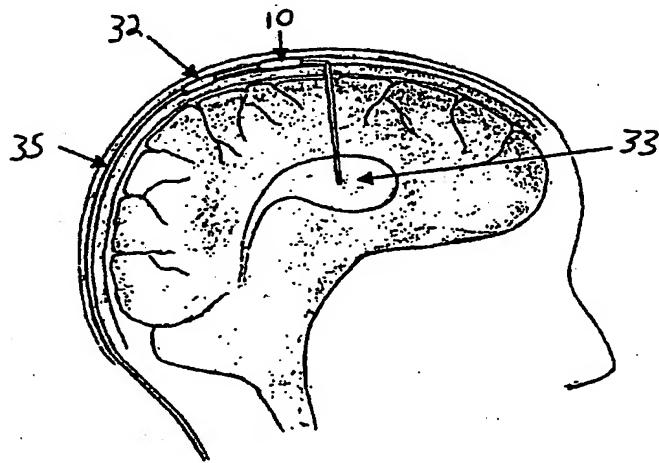
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(54) Title: **IMPLANTABLE INTRACRANIAL AND CEREBROSPINAL FLUID PRESSURE MONITOR**



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(57) Abstract: The present invention relates to a completely implantable intracranial pressure monitor (10), which can couple to existing fluid shunting systems (35) as well as other internal monitoring probes. The implant sensor produces an analog data signal which is then converted by electronic means to a digital pulse by generation of a spreading code signal and then transmitted to a location outside the patient by means of a radio-frequency transmitter (15) to an external receiver (44). The implanted device can receive power from an internal source (16) as well as an inductive external source (50). Remote control of the implant is also provided by a control receiver (60) which passes commands from an external source to the implant system logic. Alarm parameters can be programmed into the device which are capable of producing an audible or visual alarm signal. The utility of the monitor can be greatly expanded by using multiple pressure sensors simultaneously or by combining sensors of various physiological types.



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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

5 **IMPLANTABLE INTRACRANIAL AND CEREBROSPINAL FLUID PRESSURE MONITOR**10 **GOVERNMENT LICENSE RIGHTS STATEMENT**

This invention was made with United States Government support awarded by the United States Department of Energy under contract to UT-Battelle, LLC. The United States has certain rights in this invention.

15 **TECHNICAL FIELD**

The present invention relates generally to a medical device for monitoring cerebral spinal fluid pressure and relates more specifically to a miniature pressure sensor which transmits data by telemetry to an externally located receiver.

20 **BACKGROUND OF THE INVENTION**

Intracranial pressure (ICP) monitoring and control is a vital component of neurosurgical management for individuals with brain edema due to a variety of maladies, including tumor, encephalitis, meningitis, and hydrocephalus [Ivan, *Intracranial Pressure Monitoring with Fiberoptic Transducer for Children*, CHILD'S BRAIN 7: 303-313]. Shunting systems provide for pressure management of ICP but are often subject to failure due to blockage and other faults. The ability to continuously monitor ICP enables improved diagnosis and response to shunting failure, in addition to overall improved management of abnormal ICP conditions.

35 Systems exist which monitor ICP either through existing fluid shunting systems or through independent intraventricular access tubing. Because most of these systems are not fully implantable, the attached wires make continuous patient

monitoring difficult, and cables restrict patient movement. In addition, the potential for infection through the interfacial boundary to the exterior of the patient is great with such partially implantable systems. Often, due to the simplicity of their design, most partially implantable systems are inherently inaccurate and, even if initially calibrated, easily become decalibrated.

Fully implantable monitoring systems are available but suffer from a number of serious drawbacks. Currently available systems rely solely upon internally located power supplies, *i.e.*, batteries. However, once the batteries are exhausted, the device fails. Furthermore, currently available systems do not allow the simultaneous use of multiple pressure sensors or other physiological sensor combinations. Built-in programmable alarm capabilities which can warn of either mechanical/electronic problems or more serious physiological problems are also lacking in currently available monitoring systems.

Additionally, presently available implantable systems typically incorporate slow and noisy data transmission methods that are prone to interference from many sources, including nearby medical electronic equipment and systems.

Thus there is a need for a totally implantable ICP monitor which is not completely dependent upon an exhaustible internal power supply.

There is a further need for an implantable ICP monitor which can couple to existing fluid shunting systems as well as other internal monitoring probes.

There is still a further need for an implantable ICP monitor which is accurate and reliable and will not become decalibrated, even over extended periods of time.

SUMMARY OF THE INVENTION

Stated generally, the present invention relates to a completely implantable ICP monitor that is not totally dependent upon an exhaustible internal power supply. The monitor of the

present invention can couple to existing fluid shunting systems as well as other internal monitoring probes. In addition, the monitor is accurate, reliable, and will not become decalibrated, even over extended periods of time.

Stated somewhat more specifically, the present invention is a fully implantable apparatus for monitoring intracranial cerebral spinal fluid pressure. In one particular embodiment, the apparatus comprises a pressure transducer that monitors for intracranial pressure variations. The pressure transducer is coupled to a fluid handling system that can shunt excess cerebral spinal fluid (CSF) from the cerebral ventricles to a subcranial or extracranial space. The pressure transducer produces an analog data signal which is then converted by electronic means to a digital pulse stream by generation of a spreading-code signal and then transmitted outside the patient by means of a radio-frequency (RF) transmitter to an external receiver. The external receiver unit can collect generated data as well as transmit programming signals to the implanted device.

One feature of the disclosed invention is its dual powering capabilities. The implanted device can receive power from an internal source, an inductive external source, or a combination thereof. Further, alarm parameters can be programmed into the device which are capable of producing an audible or visual alarm signal.

The utility of the disclosed invention can be greatly expanded by using multiple pressure sensors simultaneously or by combining sensors of various physiological types. The use of multiple sensors provides more accurate, complete information to medical personnel.

Thus it is an object of the present invention to provide an improved implantable intracranial pressure-monitoring device.

It is another object of the present invention to provide a miniaturized measuring device and transmitter that can operate even during battery failure.

It is still yet another object of the present invention to provide a monitoring device that transmits data in such a way that multiple units can be operated in close proximity.

It is another object of the present invention to provide a compact and portable monitoring receiver that would allow freedom of movement for the patient so that the patient can participate in routine, day-to-day activities.

It is still another object of the present invention to provide a means for both monitoring CSF pressure and controlling the shunt valve.

It is yet another object of the present invention to provide a miniature CSF pressure-monitoring system with programmable alarm capability that avoids the possibility of unrecognized and potential dangerous alterations in intracranial pressure or other life-threatening conditions in the monitored patient.

It is a further object of the present invention to provide a means for multi-physiological sensing capability from a single implanted device.

A further object of the present invention is to provide a method for monitoring CSF pressure in an individual which enables the relocation and repositioning of the subject without the difficulties associated with the moving and re-attachment of cables, wires and sensors.

It is an additional object of the present invention to provide a method for monitoring CSF in a patient where said method provides a reduced risk of infection associated with invasive instruments and sensors.

It is still an additional object of the present invention to provide a practical means for remote control of the implant, by either radio or ultrasonic techniques.

Other objects, features, and advantages of the present invention will become apparent upon reading the following specification, when taken in conjunction with the drawings and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic representation of the miniaturized circuitry of the sensing unit and transceiver.

FIG. 2 is a representation of an implantable capsule showing an RF transmitter.

FIG. 3 is cross sectional representation of a patient depicting the implanted pressure sensing system attached to the fluid shunt and shunt valve.

FIG. 4 is an enlargement of the cross-sectional representation depicted in **FIG. 3**.

FIG. 5 is a sketch of the printed circuit board configuration of the energizing coil of the inductive power source.

FIG. 6 is a sketch of the inductive power pickup coil.

DETAILED DESCRIPTION OF THE DISCLOSED EMBODIMENT

Referring now to the drawings, in which like numerals indicate like elements throughout the several views, an ICP monitor 10 is composed of several functional blocks: sensors 11, signal conditioning electronics 12, a system controller 13, sensor outputs 14, an RF transmitter 15, a power source 16, device identification circuitry 18, and a data transmission antenna 22 (**FIG. 2**). Sensor outputs 14 are conditioned and digitized using the signal-conditioning electronics 12 composed of amplifiers, filters, and an analog-to-digital converter (ADC) 19.

The sensors 11 can be a single pressure transducer 42 or multiple in-line, flow-through, pressure transducers 42. Each transducer 42 may be integrally fabricated into an electronics package using integrated micro-electromechanical systems (MEMS) technology during the circuit fabrication process. Examples of materials which would be suitable for fabricating an integrated electronics package are silicon and silicon oxide.

Alternatively, the transducer may be a discrete component manufactured according to conventional sensor fabrication methodologies.

The pressure transducer 42 comprises a deflectable membrane 41. On one side of the membrane 41 is a reference chamber 46, within which exists a reference pressure condition. On the opposite side of the membrane 41 is a chamber 47 in-line with the intracranial fluid handling system, *i.e.* shunt 35. Pressure within the chamber 47 is thus the ICP. The reference chamber 46 may be fully or partially evacuated to enable measurement of negative pressure conditions relative to ambient barometric conditions. By using this configuration, ambient barometric pressure fluctuations may be observed by the intracranial pressure measurement due to any unbalanced effects between the barometric-sensitive measurement side and isolated (barometric-insensitive) reference side of the pressure sensor. To compensate for any barometric pressure effects, a barometric pressure measurement may be concurrently made external to the patient, *i.e.* within the receiving unit 44 of the telemetry system.

The shunt valve 43 can be triggered by means of an external signal from the control receiver 60 to shunt CSF away from the ventricle 33 in order to compensate for fluctuations in ICP.

Power is provided to the ICP monitor 10 by means of a power source 16 and regulated by a power managing circuit 21. The ability of a limited internal power source to deliver power can be a significant constraint, especially during times of high power consumption, *i.e.* data transmission. To overcome this limitation, powering of the disclosed system is accomplished using either of two primary methods: an internal battery or by external inductive power coupling, with or without a capacitive device as an energy storage element.

The inductive power system consists of a driving circuit 49, an energizing coil 50, and a matching circuit located within

the power managing circuit 21. The impedance of the latter circuit matches the driving circuit 49 to the antenna 22.

The energizing coil 50 produces the magnetic and electric field components that are coupled into the implant (ICP monitor) 10. This coil can be implemented a number of different ways, including but not limited to using a simple single-radius coil, or as a planarized coil fabricated in a standard printed-circuit board of single or multiple layers. If the energizing coil is constructed using wire and not on a printed circuit board, the wire may be wound using standard flat-spiral rectangular, flat-spiral circular, and jumble-wound techniques. Alternatively, the use of a circuit board for the energizing coil 50 as shown in FIG. 5 would allow for its implementation within a small, hand-held device.

The latter method, inductive power coupling, not only allows the battery to be supplemented during periods of high power consumption but also permits the battery or capacitive device to be periodically recharged using an inductive power link, thereby providing much greater flexibility and longevity of the implant.

A small energy-storage device such as a battery is located within the implant 10 and provides power to the implant during periods of normal use. Typical battery types include lithium, nickel-cadmium, or a self-contained radioactive material. During periods of increased power consumption, such as data transmission, power to the implant 10 can be induced externally with a power transmitter operated within an optimal range of typically 100 kHz and 1 MHz.

This frequency is selected for maximum power coupling into a small pickup coil 51 (FIG. 6) located within the implant 10. The coil 51 can also be either wire-wound or implemented in a planar fashion using printed-circuit board technology. The simplest coil configuration (single-radius multi-turn) is shown in FIG. 6 and may have an air core or a ferrite core, depending on the application. In addition, the coil 51 may be placed on the perimeter of the electronics circuitry shown in FIG. 1 to

maximize the area enclosed by the loop while minimizing the overall size of the implant 10. The same winding methods may be used for the pickup coil 51 that can be employed with the energizing coil 50, *i.e.* standard flat-spiral rectangular, flat-spiral circular, and jumble-wound techniques. In addition, techniques that reduce the inter-winding capacitance, including pie-wound, also can be employed.

It should be noted, however, that other embodiments of the disclosed invention would certainly permit operation outside of this frequency range.

In addition, to facilitate remote control of the various internal functions of the implant, such as power-up, power-down, forced identification, and on-demand sensor readings, a control receiver 60 is optionally provided to relay external commands to the internal system controller block 13. In the disclosed embodiment the implant 10 is housed within a system housing which protects the components and minimizes temporal calibration drift due to mechanical strain. Preferably the pressure transducer 42 and associated electronics are integral with the housing of the implant 10. Thus, mechanical strain, due to ambient pressure fluctuations, motion artifacts, and scar tissue build-up, is minimized.

In a typical functional configuration of the foregoing instrumentation, variations in intracranial pressure sensed by the pressure transducer 42 cause deflection of the membrane 41 indicative of the pressure differential between the reference chamber 46 and the local intracranial pressure as measured within the chamber 47. These deflections may be measured by extremely low-power strain-gauge measurement on the surface of the membrane 41 or by other conventional strain measurement techniques. These techniques can include, but are not limited to, piezoresistive, optoreflective, or capacitive.

The system controller 13 continuously acquires data from the various sensors stored within the instrument capsule. An analog-to-digital converter 19 digitizes the data and outputs

digitized sensor data 17 back to the system controller 13. The system controller 13 constructs a data packet from the digitized sensor data 17 and incorporates into the data packet a unique device identification number from memory storage 20. The data packets are stored, and periodically the stored data is transferred to the wireless RF transmitter 15 for transmission to the external telemetry receiver 44.

From the telemetry receiver 44, the data can be locally displayed and stored. Alternatively, data may be stored in the local data collection node until transferred to a separate or integrated computing platform for data processing, visualization, manipulation, and storage.

Alarm capabilities can be programmed into the system controller 13 to notify the patient or physician in the event of alarm conditions, *e.g.* sudden changes in ICP or decreases in pressure beyond a particular programmed threshold. Such programming of alarm parameters may be accomplished by sending programming data from an external RF transmitter to the miniaturized antenna 22 within the implant 10. In response to an alarm condition the implant 10 can also send compensatory feedback to the shunt valve 43. Thus, it is possible both to monitor CSF pressure and to compensate for fluctuations in pressure without the need for physician intervention.

Additionally, the implant 10 can incorporate other enhanced features besides data storage or alarm programming. These include data averaging/processing (*e.g.*, min/max, standard deviation) or precise functioning through preset thresholds to permit no or infrequent transmissions to the receiver 44 unless an out-of-tolerance pressure, temperature, or flow condition (or other parameter) is detected. This provides a more efficient user interface for the system and also conserves implant power. The implant 10 can also be programmed to sense time-derivatives (rates of change) of the key measured parameters (and/or combinations thereof), which can serve as precursors for vital-

signs, upsets which could indicate onset of life-threatening conditions in the monitored patient.

An important feature of the implant 10 is the incorporation of internal diagnostic and/or self-calibration functions to enhance operational accuracy and reliability. This includes monitoring battery or power-source charge or voltage.

As an additional enhancement, appropriate time-stamping of the sensor signals 14 may also be used to correlate and distinguish signals. In addition, MEMS technology can be used to reduce sensitivity to attitude, sensor motion, gravity, and vibration, all of which can reduce performance of conventional sensor technologies.

The utility of the device is further enhanced by the ability to receive remote commands by either conventional digital or spread-spectrum techniques, using either radio-frequency or ultrasonic signaling methods. This remote signal path may even be incorporated into the inductive powering system 49, 50 to provide automatic triggering of the implant to send vital telemetry data such as power-supply voltage, battery charge, and so forth. This feature also permits instant, on-demand readings of any system sensor data when desired. This remote signal may also be used for identification programming, and setting thresholding and alarm setpoints, mode selection, signal processing parameters, data collection parameters, data transmission parameters, or for selecting any other programmable variable. Use during initialization, calibration, testing, and normal operation provides for a more flexible system.

As one skilled in the art will easily appreciate, buildup of fluid upon the sensor face may degrade sensor performance. Redundancy of measurements, such as through the use of multiple in-line pressure transducers 42, will facilitate evaluation of sensor performance and will permit detection of degraded performance of a sensor. Furthermore, periodic measurements of the variation of diaphragm diameter with time will enable

signal processing to help determine the amount of buildup upon each sensor face and related decalibration of each face due to said buildup.

In addition to intracranial pressure, flow measurement of cerebral spinal fluid through the sensor 11 may be monitored by a variety of techniques, including energy-additive thermal-mass flow-metering and inertially based drag flow-meters. Thermal-mass flow-metering techniques inject heat into the flow-stream and monitor the resultant thermal change of the system. Typical low-energy methods include use of a resistive heating element into which a constant current is injected or a constant amount of power is produced. The heating element may serve a dual capacity as a thermal measuring device such as, but not limited to resistive or thermoelectric. Alternatively, a separate thermometer element may be located downstream within the flow. The resultant temperature that is measured is proportional to the mass flow of fluid across the system. Similarly heat may be injected into the flow-stream between two thermometers, and the gradient or temperature profile between the thermometers indicates mass flow across the system. Each of these techniques, and related techniques, evaluates fluid flow by measuring the effects of convective transport of heat downstream with the fluid.

Several low-power drag techniques may also be used to monitor fluid flow. Cantilevered drag bodies may be positioned within the flow stream such that strain is produced within the cantilever due to viscous drag of the fluid upon the beam. The amount of strain can be measured using deformation measurement techniques, similar to those used for the pressure sensing diaphragm (piezoresistive, optoreflective, capacitive).

Total flow values may be measured by summing the amount of flow through the sensing system over an interval of time. This information reveals total amount of CSF flow through the system, providing important diagnostic information for patient monitoring.

Another unique capability of the disclosed invention is the ability to integrate and combine additional modes of physiological measurements. For example, in addition to pressure measurement, integrated temperature measurement may be included, based on either a proportional-to-absolute-temperature (PTAT) device or a p-n junction (V_{BE}) or some combination of the two sensors. Other types of temperature measurement could be easily incorporated in other embodiments without departing from the scope of the disclosed invention. Similarly, other measurements may include, but are not limited to: an optical sensor that determines both saturated blood oxygen level and pulse detection using standard pulse oximetry techniques, a pH sensor, a pO_2 sensor, a pCO_2 sensor, or an dihydronicotinamide adenine dinucleotide (NADH) sensor. In addition, the instrument platform facilitates the addition of other sensor types including, but not limited to acoustic, piezoresistive, biochemical, electrochemical, and conductive.

The implant 10 of the disclosed preferred embodiment has an on-chip direct-sequence spread-spectrum wireless RF transmitter 15, typically operating within one of the FCC-designated Industrial, Scientific, and Medical (ISM) designated bands, such as that around 915 MHz. Unique signal spreading codes can be generated with standard digital logic devices using a selectable family of mutually orthogonal polynomials in either standard linear (*i.e.*, maximal-length sequence, Gold, or Kasami codes) or nonlinear (more secure) formats. The use of *orthogonal* spreading codes permits the use of multiple units in close proximity, *i.e.* within the same or nearby individual subjects, via the application of frequency-division (FDMA), time-division (TDMA), or code-division (CDMA) multiple-access techniques, similar to those employed in cellular telephone systems and well known in the communications art. These techniques may also be used in combination to provide improved performance and great flexibility in multiple-device implementations. The currently known digital data and/or spread-

spectrum chipping modulation techniques which can be utilized herein include: frequency-shift keying (FSK); phase-shift keying (PSK); amplitude-shift keying (ASK); on-off keying (OOK); quadrature phase-shift keying (QPSK); offset quadrature phase-shift keying (OQPSK); minimum-shift keying (MSK); n -state quadrature amplitude modulation (n -QAM, i.e., 4-QAM, 16-QAM, 64-QAM, etc.); binary phase-shift keying (BPSK); multiple-state phase-shift keying (MPSK); multiple-state frequency-shift keying (MFSK); FM chirp modulation, pulse-time modulation, and many others.

Additionally, the capsule electronic chip 21 can include a radio-frequency synthesizer incorporated within the RF transmitter 15, which would permit precise digital selection of a number of frequencies in the band of interest. These ISM frequency bands in which RF devices are typically employed generally do not require licensing to operate so long as certain power and spectral-emission specifications are maintained. These bands are from 902-928 MHz, 2400-2483.5 MHz, 5150-5250 MHz, 5250-5350 MHz and 5725-5825 MHz. Additionally, other bands in the very-high frequency (VHF), ultra-high frequency (UHF), and microwave frequency (> 1 GHz) ranges can be used, and still others are currently proposed for medical equipment use and/or computer-networking use (typically above 5 GHz). Unfortunately, severe interference from television broadcast transmitters has been experienced with conventional RF medical telemetry devices when operated at some of these frequencies. Spread-spectrum systems such as those employed in the disclosed invention will eliminate these highly undesirable interference problems in both hospital/clinical and home settings. Furthermore, properly implemented spread-spectrum RF devices will dramatically reduce the likelihood of causing potentially dangerous interference to existing nearby sensitive medical electronic devices and systems.

Another major benefit of spread-spectrum modulation for the disclosed embodiment of the invention is its ability to reject

most levels of multi-path interference which can acutely and adversely limit the data quality in conventional narrow-band data-modulation schemes. To overcome this possible limitation, the preferred form of the disclosed invention utilizes direct-sequence spread-spectrum (DSSS), which can markedly reduce almost all errors caused by multi-path reflections, since the corresponding differential time delays due to the aforementioned multi-path reflections are typically greater than the DSSS chipping-sequence interval and are therefore ignored in the demodulation process. In addition, and preferably, the disclosed device can simultaneously employ time-, frequency-, and code-division multiplexing to achieve extremely effective channel separation for multiple-sensor applications.

Besides DSSS, other means of spread-spectrum spreading code techniques currently known in the art include time- and frequency-hopping modulation. Time-hopping (TH) refers to changing the timing of the bursts or pulses of streaming data so that it will transmitted in a pseudo-random fashion. Frequency-hopping (FH) permits the ability to "hop" or change the carrier frequency of the RF transmission in accord with pseudo-random p-n codes. It is extremely useful in real-world settings to employ combinations of these modulations; e.g., DSSS/FH, DSSS/TH (or more commonly denoted, *DS/FH* and *DS/TH*) to much more effectively counteract interference and multipath effects and simultaneously provide greater flexibility in configuring multi-sensor and/or multi-user scenarios in clinical settings.

The use of highly robust spread-spectrum RF techniques for data transmission also permits the monitoring receiver 44 to take the form of a portable pocket, pager, or belt-worn unit which could accompany the patient in routine, day-to-day activities such as school, travel, shopping, etc. away from the clinical environment. Emergency data and alarms could then be automatically relayed via cellular networks, modems, or the like, for remote medical analysis, while key patient data is simultaneously archived and stored for detailed post-analysis.

The spread-spectrum RF system can also, via its substantial immunity to multi-path effects (caused for example by patient motion or environmental changes), facilitate the use of extremely high RF transmission frequencies. Thus, frequencies well above 1 GHz, by virtue of their short wavelengths (centimeters or less), will enable the development of very compact, yet reasonably efficient antenna structures within the tiny envelopes useful for unobtrusive micro-miniature implantable monitoring and/or treatment devices. At these very short RF signal wavelengths, spread-spectrum transmission can effectively compensate for sharp drop-out nulls caused by even minor head motions and provide error-free data transmission in even highly noisy, interference-prone signal-propagation conditions. The spread-spectrum RF transmitter also can be implemented to function ultrasonically to increase its efficiency.

Furthermore, by combining the use of multiple implanted sensors with available networking technologies, the implants can be used as a networked monitoring system.

Finally, it will be understood that the preferred embodiment has been disclosed by way of example, and that other modifications may occur to those skilled in the art without departing from the scope and spirit of the appended claims.

CLAIMS

What is claimed is:

1. An apparatus for monitoring intra-cranial cerebral spinal fluid pressure in a subject, said apparatus comprising

a sensor for sensing intracranial pressure;
control means for collecting data from said sensor
corresponding to sensed intracranial pressure;
a spread-spectrum transmitter;
means for communicating said data from said control
means to said transmitter;
a power source for powering said sensor and said
control means.

2. The apparatus of Claim 1 wherein said sensor is a pressure transducer comprising a deflectable membrane having one side of the membrane monitoring a reference pressure condition and the opposite side of the membrane coupled to a chamber of a fluid-handling system.

3. The apparatus of Claim 1 wherein said sensor comprises one or more pressure transducers in combination.

4. The apparatus of Claim 1 wherein said spread-spectrum transmitter is a radio-frequency transmitter that operates in one or more frequency ranges of 902 - 928 MHz, 2450 - 2483.5 MHz, 5150 - 5250 MHz, 5250 - 5350 MHz, and 5725 - 5825 MHz.

5. The apparatus of Claim 1 wherein said spread-spectrum transmitter is a radio-frequency transmitter that operates at frequency of approximately 915 MHz.

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6. The apparatus of Claim 1 wherein said spread-spectrum transmitter is an ultrasonic transmitter.

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7. The apparatus of Claim 1 wherein said power source is one or more batteries of the type selected from the group consisting of lithium, nickel-cadmium, and a self-contained radioactive material.

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8. The apparatus of Claim 1 wherein said power source is a capacitive element.

9. The apparatus of Claim 1 wherein said power source receives inductive power from an inductive power source which operates at a frequency less than 100 kHz.

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10. The apparatus of Claim 1 wherein said power source receives inductive power from an inductive power source which operates at a frequency greater than 1 MHz.

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11. The apparatus of Claim 1 wherein said power source receives inductive power from an inductive power source which operates at a frequency range of 100 kHz to 1 MHz.

12. The apparatus of Claim 1 wherein said data is transmitted to an external receiver by generation of a spreading-through spread-spectrum modulation, wherein said spread-spectrum modulation comprises, alone or in combination, direct-sequence modulation, frequency-hopping modulation, and time-hopping modulation.

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13. The apparatus of Claim 2 wherein said fluid-handling system is controlled by a signal received from an external source.

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14. The apparatus of Claim 1 further comprising an audible or visual alarm signal.

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15. The apparatus of Claim 1 further comprising a receiving means for receiving control commands from an external source.

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16. A monitoring apparatus in a subject, said apparatus comprising:

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a sensor for sensing a physiological parameter;
control means for collecting data from said sensor
corresponding to a sensed physiological parameter;
a spread-spectrum transmitter;
means for communicating said data from said control
means to said transmitter;

a power source for powering said sensor and said
control means.

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17. The apparatus of Claim 16 wherein said sensor monitors cerebral spinal fluid flow through thermal-mass flow.

18. The apparatus of Claim 16 wherein said sensor monitors cerebral spinal fluid flow through inertial-drag flow.

5 19. The apparatus of Claim 16 wherein said sensor is selected from the group consisting of: acoustic, piezoresistive, biochemical, electrochemical, electrical and conductive.

10 20. The apparatus of Claim 16 wherein said spread-spectrum transmitter is a radio frequency transmitter that operates in one or more frequency ranges of 902 - 928 MHz, 2450 - 2483.5 MHz, 5150 - 5250 MHz, 5250 - 5350 MHz, and 5725 - 5825 MHz.

15 21. The apparatus of Claim 16 wherein said spread-spectrum transmitter is a radio frequency transmitter that operates at a frequency of approximately 915 MHz.

20 22. The apparatus of Claim 16 wherein said spread-spectrum transmitter is an ultrasonic transmitter.

25 23. The apparatus of Claim 16 wherein said power source is one or more batteries of the type selected from the group consisting of lithium, nickel-cadmium, and a self-contained radioactive material.

24. The apparatus of Claim 16 wherein said power source is a capacitive element.

25. The apparatus of Claim 16 wherein said power source receives inductive power from an inductive power source which operates at a frequency less than 100 kHz.

5 26. The apparatus of Claim 16 wherein said power source receives inductive power from an inductive power source which operates at a frequency greater than 1 MHz.

10 27. The apparatus of Claim 16 wherein said power source receives inductive power from an inductive power source which operates at a frequency range of 100 kHz to 1 MHz.

15 28. The apparatus of Claim 16 wherein said data is transmitted to an external receiver through spread-spectrum modulation, wherein said spread-spectrum modulation comprises, alone or in combination, direct-sequence modulation, frequency-hopping modulation, and time-hopping modulation.

20 29. The apparatus of Claim 16 capable of producing an audible or visual alarm signal.

25 30. The apparatus of Claim 16 used in combination, in one or more subjects, said combination transmitting data through multiple-access spread-spectrum modulation comprising code-division, frequency-division, and time-division multiplexing.

31. The apparatus of Claim 30, wherein said multiple-access-spread-spectrum modulation comprises frequency-shift keying, phase-shift keying, amplitude-shift keying, on-off keying, quadrature phase-shift keying, offset quadrature phase-shift keying, minimum-shift keying, n -state quadrature amplitude modulation, binary phase-shift keying; multiple-state phase-shift keying, multiple-state frequency-shift keying, frequency-modulation chirp modulation, and pulse-time modulation.

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32. The apparatus of Claims 16 further comprising receiving means for receiving control commands from an external source.

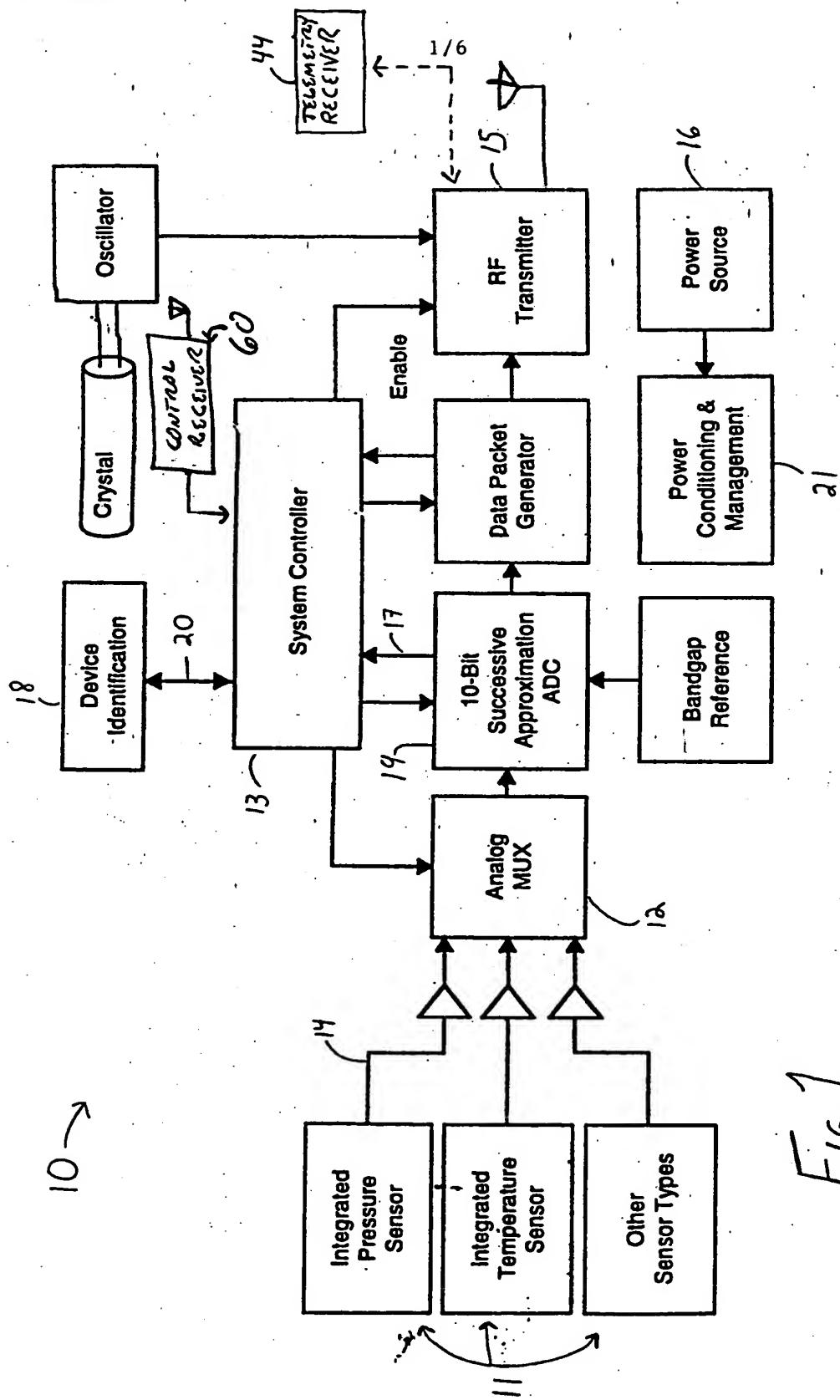
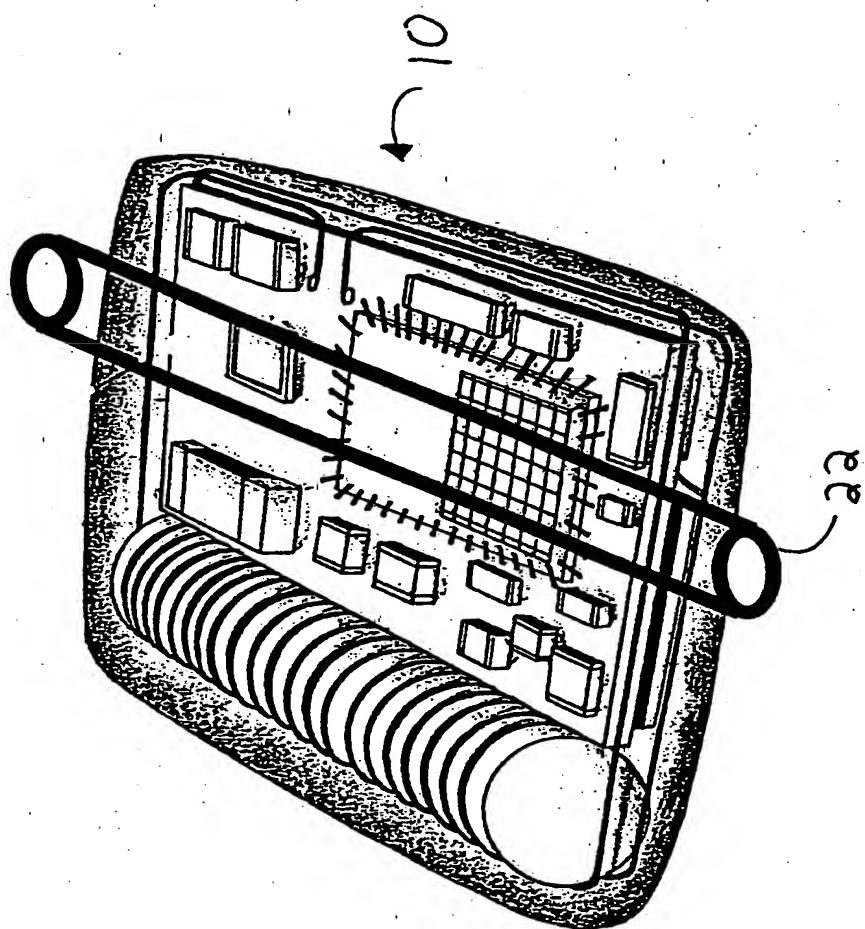


FIG 1

2/6



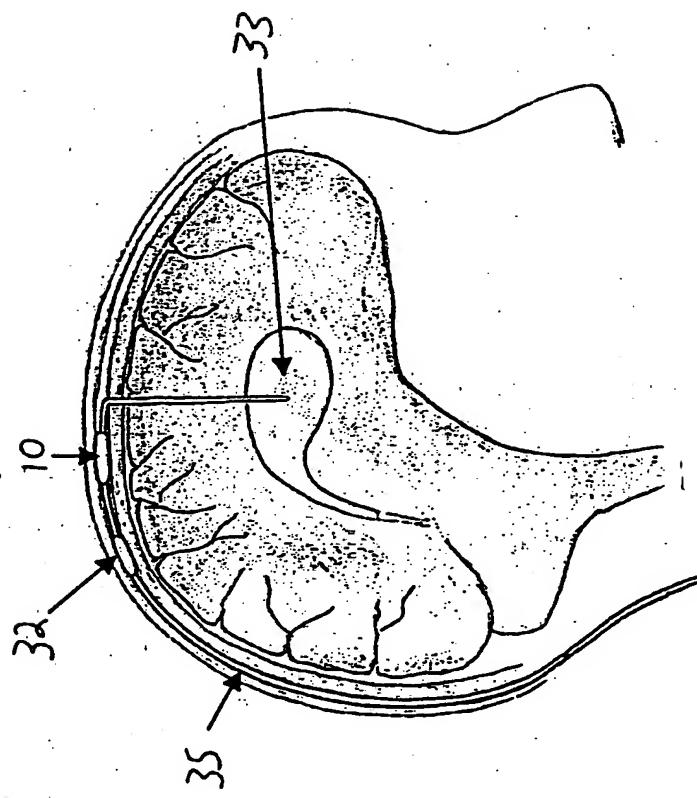


Fig. 3

4/6

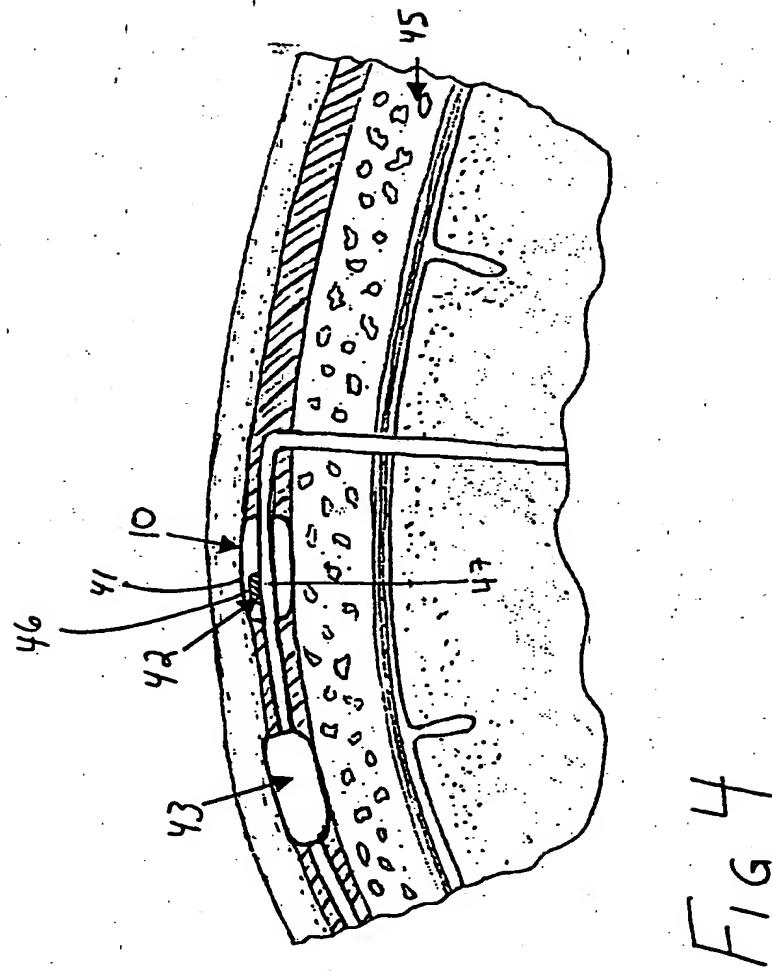


FIG 4

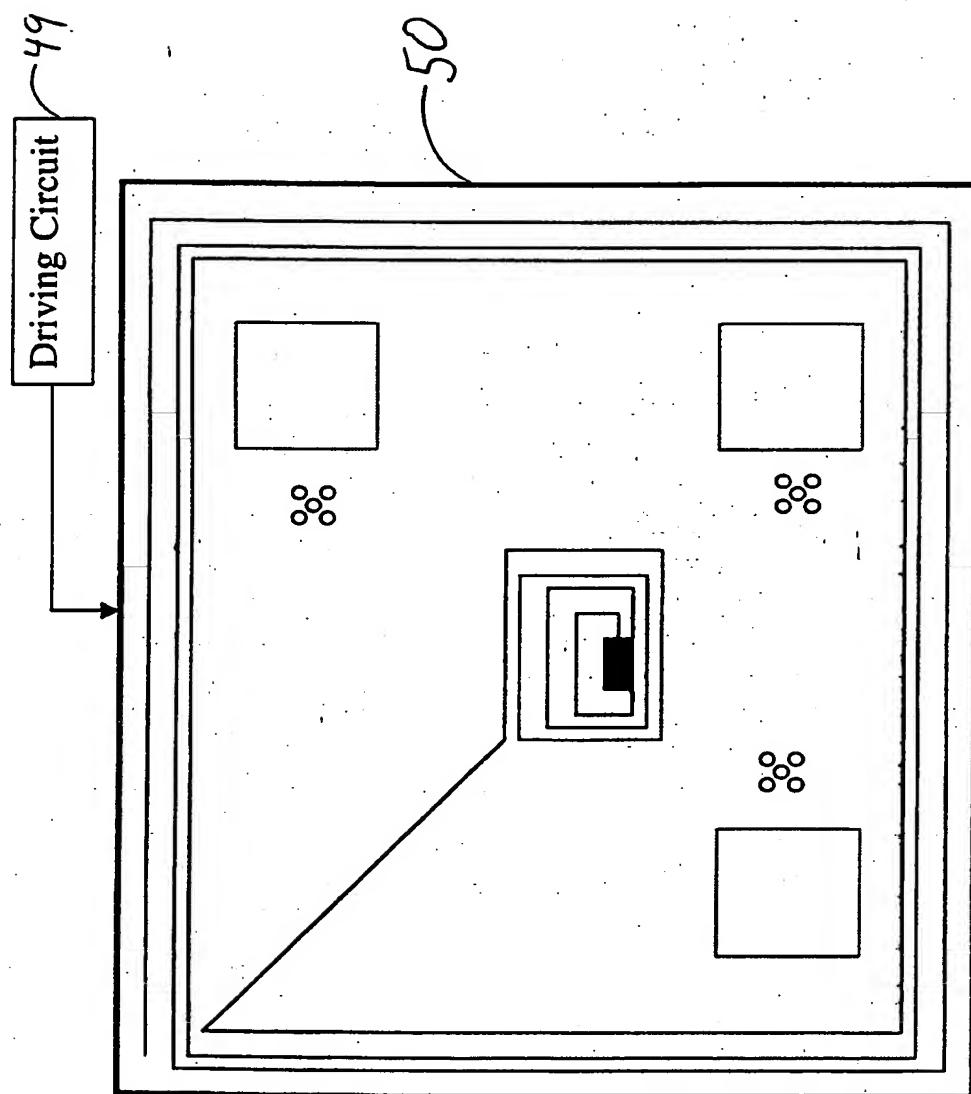


FIG. 5

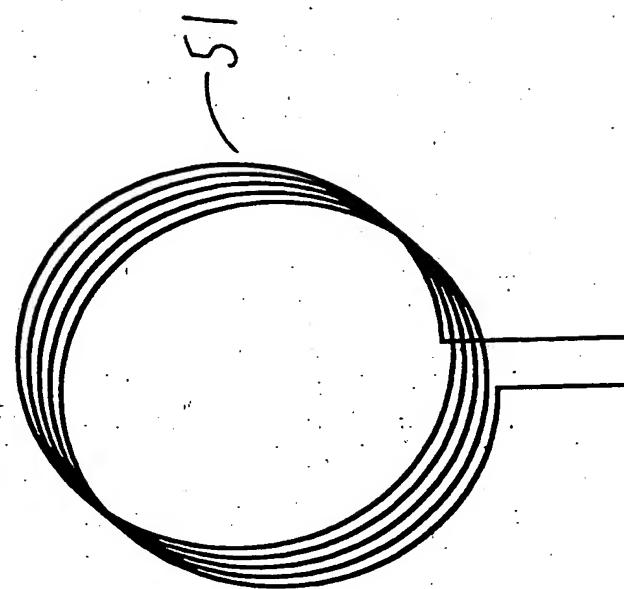


FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/26168

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/03 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, COMPENDEX, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	B -FLICK B ET AL.: "Study and development of a portable telemetric intracranial pressure measurement unit" PROCEEDINGS OF THE 19TH ANNUAL INTERNATIONAL CONFERENCE OF THE IEEE ENGINEERING IN MEDICINE AND BIOLOGY SOCIETY. 'MAGNIFICENT MILESTONES AND EMERGING OPPORTUNITIES IN MEDICAL ENGINEERING' (CAT. NO. 97CH36136) CHICAGO, IL, USA, 30 OCT.-2 NOV. 1997, vol. 3, 1997, pages 977-980, XP002156869 NY, USA abstract page 977, left-hand column, line 4 - 7 sections "II. METHODS" and "III. RESULTS"	1, 3-7, 12, 15, 16, 19-23, 28, 32
A	—/—	14, 29

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
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- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

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INTERNATIONAL SEARCH REPORT

Internal Application No

PCT/US 00/26168

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	column 9, line 11 - line 46 column 3, line 19 - line 40	9-11, 25-27,30
Y	US 5 767 791 A (FLACH TERRY E. ET AL) 16 June 1998 (1998-06-16)	1,3-5,7, 12,15, 16, 19-21, 23,28,32
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Y	EP 0 864 293 A (HEWLETT PACKARD CO) 16 September 1998 (1998-09-16)	1,3,6, 12,15, 16,22, 28,32
	column 4, line 38 - line 44 column 1, line 16 - line 37	
A	WO 97 33513 A (LIPOMATRIX INC) 18 September 1997 (1997-09-18)	1-3,8, 15,16, 24,32
	page 20, line 24 - line 31 page 10, line 32 -page 11, line 31 page 28, line 21 -page 29, line 10	
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	-/-	

INTERNATIONAL SEARCH REPORTInternal Application No
PCT/US 00/26168**C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 691 709 A (COHEN DONALD M) 8 September 1987 (1987-09-08) column 1, line 67 -column 2, line 8 column 4, line 65 -column 5, line 19	1,16,18

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Information on patent family members

Internal Application No

PCT/US 00/26168

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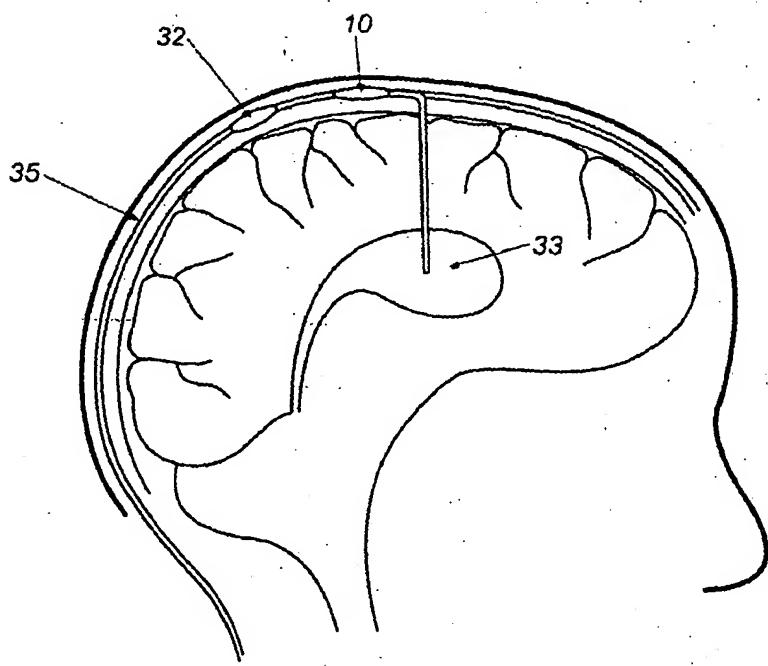
(74) Agents: **ROBERTS, Larry, A. et al.**; Kilpatrick Stockton LLP, 2400 Monarch Tower, 3424 Peachtree Road, N.E., Atlanta, GA 30326 (US).

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[Continued on next page]

(54) Title: **IMPLANTABLE INTRACRANIAL AND CEREBROSPINAL FLUID PRESSURE MONITOR**



(57) Abstract: The present invention relates to a completely implantable intracranial pressure monitor (10), which can couple to existing fluid shunting systems (35) as well as other internal monitoring probes. The implant sensor produces an analog data signal which is then converted by electronic means to a digital pulse by generation of a spreading code signal and then transmitted to a location outside the patient by means of a radio-frequency transmitter (15) to an external receiver (44). The implanted device can receive power from an internal source (16) as well as an inductive external source (50). Remote control of the implant is also provided by a control receiver (60) which passes commands from an external source to the implant system logic. Alarm parameters can be programmed into the device which are capable of producing an audible or visual alarm signal. The utility of the monitor can be greatly expanded by using multiple pressure sensors simultaneously or by combining sensors of various physiological types.

WO 01/021066 A1



patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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5

IMPLANTABLE INTRACRANIAL AND CEREBROSPINAL FLUID PRESSURE MONITOR

10

GOVERNMENT LICENSE RIGHTS STATEMENT

This invention was made with United States Government support awarded by the United States Department of Energy under contract to UT-Battelle, LLC. The United States has certain rights in this invention.

15

TECHNICAL FIELD

The present invention relates generally to a medical device for monitoring cerebral spinal fluid pressure and relates more specifically to a miniature pressure sensor which transmits data by telemetry to an externally located receiver.

20

BACKGROUND OF THE INVENTION

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Intracranial pressure (ICP) monitoring and control is a vital component of neurosurgical management for individuals with brain edema due to a variety of maladies, including tumor, encephalitis, meningitis, and hydrocephalus [Ivan, *Intracranial Pressure Monitoring with Fiberoptic Transducer for Children*, CHILD'S BRAIN 7: 303-313]. Shunting systems provide for pressure management of ICP but are often subject to failure due to blockage and other faults. The ability to continuously monitor ICP enables improved diagnosis and response to shunting failure, in addition to overall improved management of abnormal ICP conditions.

30

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Systems exist which monitor ICP either through existing fluid shunting systems or through independent intraventricular access tubing. Because most of these systems are not fully implantable, the attached wires make continuous patient

monitoring difficult, and cables restrict patient movement. In addition, the potential for infection through the interfacial boundary to the exterior of the patient is great with such partially implantable systems. Often, due to the simplicity of their design, most partially implantable systems are inherently inaccurate and, even if initially calibrated, easily become decalibrated.

Fully implantable monitoring systems are available but suffer from a number of serious drawbacks. Currently available systems rely solely upon internally located power supplies, *i.e.*, batteries. However, once the batteries are exhausted, the device fails. Furthermore, currently available systems do not allow the simultaneous use of multiple pressure sensors or other physiological sensor combinations. Built-in programmable alarm capabilities which can warn of either mechanical/electronic problems or more serious physiological problems are also lacking in currently available monitoring systems.

Additionally, presently available implantable systems typically incorporate slow and noisy data transmission methods that are prone to interference from many sources, including nearby medical electronic equipment and systems.

Thus there is a need for a totally implantable ICP monitor which is not completely dependent upon an exhaustible internal power supply.

There is a further need for an implantable ICP monitor which can couple to existing fluid shunting systems as well as other internal monitoring probes.

There is still a further need for an implantable ICP monitor which is accurate and reliable and will not become decalibrated, even over extended periods of time.

SUMMARY OF THE INVENTION

Stated generally, the present invention relates to a completely implantable ICP monitor that is not totally dependent upon an exhaustible internal power supply. The monitor of the

present invention can couple to existing fluid shunting systems as well as other internal monitoring probes. In addition, the monitor is accurate, reliable, and will not become decalibrated, even over extended periods of time.

5 Stated somewhat more specifically, the present invention is a fully implantable apparatus for monitoring intracranial cerebral spinal fluid pressure. In one particular embodiment, the apparatus comprises a pressure transducer that monitors for intracranial pressure variations. The pressure transducer is coupled to a fluid handling system that can shunt excess cerebral spinal fluid (CSF) from the cerebral ventricles to a subcranial or extracranial space. The pressure transducer produces an analog data signal which is then converted by electronic means to a digital pulse stream by generation of a spreading-code signal and then transmitted outside the patient by means of a radio-frequency (RF) transmitter to an external receiver. The external receiver unit can collect generated data as well as transmit programming signals to the implanted device.

10 15 One feature of the disclosed invention is its dual powering capabilities. The implanted device can receive power from an internal source, an inductive external source, or a combination thereof. Further, alarm parameters can be programmed into the device which are capable of producing an audible or visual alarm signal.

20 25 The utility of the disclosed invention can be greatly expanded by using multiple pressure sensors simultaneously or by combining sensors of various physiological types. The use of multiple sensors provides more accurate, complete information to medical personnel.

30 Thus it is an object of the present invention to provide an improved implantable intracranial pressure-monitoring device.

It is another object of the present invention to provide a miniaturized measuring device and transmitter that can operate even during battery failure.

It is still yet another object of the present invention to provide a monitoring device that transmits data in such a way that multiple units can be operated in close proximity.

5 It is another object of the present invention to provide a compact and portable monitoring receiver that would allow freedom of movement for the patient so that the patient can participate in routine, day-to-day activities.

10 It is still another object of the present invention to provide a means for both monitoring CSF pressure and controlling the shunt valve.

15 It is yet another object of the present invention to provide a miniature CSF pressure-monitoring system with programmable alarm capability that avoids the possibility of unrecognized and potential dangerous alterations in intracranial pressure or other life-threatening conditions in the monitored patient.

It is a further object of the present invention to provide a means for multi-physiological sensing capability from a single implanted device.

20 A further object of the present invention is to provide a method for monitoring CSF pressure in an individual which enables the relocation and repositioning of the subject without the difficulties associated with the moving and re-attachment of cables, wires and sensors.

25 It is an additional object of the present invention to provide a method for monitoring CSF in a patient where said method provides a reduced risk of infection associated with invasive instruments and sensors.

30 It is still an additional object of the present invention to provide a practical means for remote control of the implant, by either radio or ultrasonic techniques.

Other objects, features, and advantages of the present invention will become apparent upon reading the following specification, when taken in conjunction with the drawings and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic representation of the miniaturized circuitry of the sensing unit and transceiver.

FIG. 2 is a representation of an implantable capsule showing an RF transmitter.

FIG. 3 is cross sectional representation of a patient depicting the implanted pressure sensing system attached to the fluid shunt and shunt valve.

FIG. 4 is an enlargement of the cross-sectional representation depicted in FIG. 3.

FIG. 5 is a sketch of the printed circuit board configuration of the energizing coil of the inductive power source.

FIG. 6 is a sketch of the inductive power pickup coil.

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DETAILED DESCRIPTION OF THE DISCLOSED EMBODIMENT

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Referring now to the drawings, in which like numerals indicate like elements throughout the several views, an ICP monitor 10 is composed of several functional blocks: sensors 11, signal conditioning electronics 12, a system controller 13, sensor outputs 14, an RF transmitter 15, a power source 16, device identification circuitry 18, and a data transmission antenna 22 (FIG. 2). Sensor outputs 14 are conditioned and digitized using the signal-conditioning electronics 12 composed of amplifiers, filters, and an analog-to-digital converter (ADC) 19.

25

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The sensors 11 can be a single pressure transducer 42 or multiple in-line, flow-through, pressure transducers 42. Each transducer 42 may be integrally fabricated into an electronics package using integrated micro-electromechanical systems (MEMS) technology during the circuit fabrication process. Example of materials which would be suitable for fabricating an integrated electronics package are silicon and silicon oxide.

Alternatively, the transducer may be a discrete component manufactured according to conventional sensor fabrication methodologies.

The pressure transducer 42 comprises a deflectable membrane 41. On one side of the membrane 41 is a reference chamber 46, within which exists a reference pressure condition. On the opposite side of the membrane 41 is a chamber 47 in-line with the intracranial fluid handling system, *i.e.* shunt 35. Pressure within the chamber 47 is thus the ICP. The reference chamber 46 may be fully or partially evacuated to enable measurement of negative pressure conditions relative to ambient barometric conditions. By using this configuration, ambient barometric pressure fluctuations may be observed by the intracranial pressure measurement due to any unbalanced effects between the barometric-sensitive measurement side and isolated (barometric-insensitive) reference side of the pressure sensor. To compensate for any barometric pressure effects, a barometric pressure measurement may be concurrently made external to the patient, *i.e.* within the receiving unit 44 of the telemetry system.

The shunt valve 43 can be triggered by means of an external signal from the control receiver 60 to shunt CSF away from the ventricle 33 in order to compensate for fluctuations in ICP.

Power is provided to the ICP monitor 10 by means of a power source 16 and regulated by a power managing circuit 21. The ability of a limited internal power source to deliver power can be a significant constraint, especially during times of high power consumption, *i.e.* data transmission. To overcome this limitation, powering of the disclosed system is accomplished using either of two primary methods: an internal battery or by external inductive power coupling, with or without a capacitive device as an energy storage element.

The inductive power system consists of a driving circuit 49, an energizing coil 50, and a matching circuit located within

the power managing circuit 21. The impedance of the latter circuit matches the driving circuit 49 to the antenna 22.

The energizing coil 50 produces the magnetic and electric field components that are coupled into the implant (ICP monitor) 10. This coil can be implemented a number of different ways, including but not limited to using a simple single-radius coil, or as a planarized coil fabricated in a standard printed-circuit board of single or multiple layers. If the energizing coil is constructed using wire and not on a printed circuit board, the wire may be wound using standard flat-spiral rectangular, flat-spiral circular, and jumble-wound techniques. Alternatively, the use of a circuit board for the energizing coil 50 as shown in FIG. 5 would allow for its implementation within a small, hand-held device!

The latter method, inductive power coupling, not only allows the battery to be supplemented during periods of high power consumption but also permits the battery or capacitive device to be periodically recharged using an inductive power link, thereby providing much greater flexibility and longevity of the implant.

A small energy-storage device such as a battery is located within the implant 10 and provides power to the implant during periods of normal use. Typical battery types include lithium, nickel-cadmium, or a self-contained radioactive material. During periods of increased power consumption, such as data transmission, power to the implant 10 can be induced externally with a power transmitter operated within an optimal range of typically 100 kHz and 1 MHz.

This frequency is selected for maximum power coupling into a small pickup coil 51 (FIG. 6) located within the implant 10. The coil 51 can also be either wire-wound or implemented in a planar fashion using printed-circuit board technology. The simplest coil configuration (single-radius multi-turn) is shown in FIG. 6 and may have an air core or a ferrite core, depending on the application. In addition, the coil 51 may be placed on the perimeter of the electronics circuitry shown in FIG. 1 to

maximize the area enclosed by the loop while minimizing the overall size of the implant 10. The same winding methods may be used for the pickup coil 51 that can be employed with the energizing coil 50, *i.e.* standard flat-spiral rectangular, flat-spiral circular, and jumble-wound techniques. In addition, techniques that reduce the inter-winding capacitance, including pie-wound, also can be employed.

5

It should be noted, however, that other embodiments of the disclosed invention would certainly permit operation outside of this frequency range.

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In addition, to facilitate remote control of the various internal functions of the implant, such as power-up, power-down, forced identification, and on-demand sensor readings, a control receiver 60 is optionally provided to relay external commands to the internal system controller block 13. In the disclosed embodiment the implant 10 is housed within a system housing which protects the components and minimizes temporal calibration drift due to mechanical strain. Preferably the pressure transducer 42 and associated electronics are integral with the housing of the implant 10. Thus, mechanical strain, due to ambient pressure fluctuations, motion artifacts, and scar tissue build-up, is minimized.

25

30

In a typical functional configuration of the foregoing instrumentation, variations in intracranial pressure sensed by the pressure transducer 42 cause deflection of the membrane 41 indicative of the pressure differential between the reference chamber 46 and the local intracranial pressure as measured within the chamber 47. These deflections may be measured by extremely low-power strain-gauge measurement on the surface of the membrane 41 or by other conventional strain measurement techniques. These techniques can include, but are not limited to, piezoresistive, optoreflective, or capacitive.

35

The system controller 13 continuously acquires data from the various sensors stored within the instrument capsule. An analog-to-digital converter 19 digitizes the data and outputs

5 digitized sensor data 17 back to the system controller 13. The system controller 13 constructs a data packet from the digitized sensor data 17 and incorporates into the data packet a unique device identification number from memory storage 20. The data packets are stored, and periodically the stored data is transferred to the wireless RF transmitter 15 for transmission to the external telemetry receiver 44.

10 From the telemetry receiver 44, the data can be locally displayed and stored. Alternatively, data may be stored in the local data collection node until transferred to a separate or integrated computing platform for data processing, visualization, manipulation, and storage.

15 Alarm capabilities can be programmed into the system controller 13 to notify the patient or physician in the event of alarm conditions, e.g. sudden changes in ICP or decreases in pressure beyond a particular programmed threshold. Such programming of alarm parameters may be accomplished by sending programming data from an external RF transmitter to the miniaturized antenna 22 within the implant 10. In response to an alarm condition the implant 10 can also send compensatory feedback to the shunt valve 43. Thus, it is possible both to monitor CSF pressure and to compensate for fluctuations in pressure without the need for physician intervention.

20 Additionally, the implant 10 can incorporate other enhanced features besides data storage or alarm programming. These include data averaging/processing (e.g., min/max, standard deviation) or precise functioning through preset thresholds to permit no or infrequent transmissions to the receiver 44 unless an out-of-tolerance pressure, temperature, or flow condition (or other parameter) is detected. This provides a more efficient user interface for the system and also conserves implant power. The implant 10 can also be programmed to sense time-derivatives (rates of change) of the key measured parameters (and/or combinations thereof), which can serve as precursors for vital-

signs upsets which could indicate onset of life-threatening conditions in the monitored patient.

An important feature of the implant 10 is the incorporation of internal diagnostic and/or self-calibration functions to enhance operational accuracy and reliability. This includes monitoring battery or power-source charge or voltage.

As an additional enhancement, appropriate time-stamping of the sensor signals 14 may also be used to correlate and distinguish signals. In addition, MEMS technology can be used to reduce sensitivity to attitude, sensor motion, gravity, and vibration, all of which can reduce performance of conventional sensor technologies.

The utility of the device is further enhanced by the ability to receive remote commands by either conventional digital or spread-spectrum techniques, using either radio-frequency or ultrasonic signaling methods. This remote signal path may even be incorporated into the inductive powering system 49, 50 to provide automatic triggering of the implant to send vital telemetry data such as power-supply voltage, battery charge, and so forth. This feature also permits instant, on-demand readings of any system sensor data when desired. This remote signal may also be used for identification programming, and setting thresholding and alarm setpoints, mode selection, signal processing parameters, data collection parameters, data transmission parameters, or for selecting any other programmable variable. Use during initialization, calibration, testing, and normal operation provides for a more flexible system.

As one skilled in the art will easily appreciate, buildup of fluid upon the sensor face may degrade sensor performance. Redundancy of measurements, such as through the use of multiple in-line pressure transducers 42, will facilitate evaluation of sensor performance and will permit detection of degraded performance of a sensor. Furthermore, periodic measurements of the variation of diaphragm diameter with time will enable

signal processing to help determine the amount of buildup upon each sensor face and related decalibration of each face due to said buildup.

In addition to intracranial pressure, flow measurement of cerebral spinal fluid through the sensor 11 may be monitored by a variety of techniques, including energy-additive thermal-mass flow-metering and inertially based drag flow-meters. Thermal-mass flow-metering techniques inject heat into the flow-stream and monitor the resultant thermal change of the system. Typical low-energy methods include use of a resistive heating element into which a constant current is injected or a constant amount of power is produced. The heating element may serve a dual capacity as a thermal measuring device such as, but not limited to resistive or thermoelectric. Alternatively, a separate thermometer element may be located downstream within the flow. The resultant temperature that is measured is proportional to the mass flow of fluid across the system. Similarly heat may be injected into the flow-stream between two thermometers, and the gradient or temperature profile between the thermometers indicates mass flow across the system. Each of these techniques, and related techniques, evaluates fluid flow by measuring the effects of convective transport of heat downstream with the fluid.

Several low-power drag techniques may also be used to monitor fluid flow. Cantilevered drag bodies may be positioned within the flow stream such that strain is produced within the cantilever due to viscous drag of the fluid upon the beam. The amount of strain can be measured using deformation measurement techniques, similar to those used for the pressure sensing diaphragm (piezoresistive, optoreflective, capacitive).

Total flow values may be measured by summing the amount of flow through the sensing system over an interval of time. This information reveals total amount of CSF flow through the system, providing important diagnostic information for patient monitoring.

Another unique capability of the disclosed invention is the ability to integrate and combine additional modes of physiological measurements. For example, in addition to pressure measurement, integrated temperature measurement may be included, based on either a proportional-to-absolute-temperature (PTAT) device or a p-n junction (V_{BE}) or some combination of the two sensors. Other types of temperature measurement could be easily incorporated in other embodiments without departing from the scope of the disclosed invention. Similarly, other measurements may include, but are not limited to: an optical sensor that determines both saturated blood oxygen level and pulse detection using standard pulse oximetry techniques, a pH sensor, a pO_2 sensor, a pCO_2 sensor, or an dihydronicotinamide adenine dinucleotide (NADH) sensor. In addition, the instrument platform facilitates the addition of other sensor types including, but not limited to acoustic, piezoresistive, biochemical, electrochemical, and conductive.

The implant 10 of the disclosed preferred embodiment has an on-chip direct-sequence spread-spectrum wireless RF transmitter 15, typically operating within one of the FCC-designated Industrial, Scientific, and Medical (ISM) designated bands, such as that around 915 MHz. Unique signal spreading codes can be generated with standard digital logic devices using a selectable family of mutually orthogonal polynomials in either standard linear (*i.e.*, maximal-length sequence, Gold, or Kasami codes) or nonlinear (more secure) formats. The use of *orthogonal* spreading codes permits the use of multiple units in close proximity, *i.e.* within the same or nearby individual subjects, via the application of frequency-division (FDMA), time-division (TDMA), or code-division (CDMA) multiple-access techniques, similar to those employed in cellular telephone systems and well known in the communications art. These techniques may also be used in combination to provide improved performance and great flexibility in multiple-device implementations. The currently known digital data and/or spread-

spectrum chipping modulation techniques which can be utilized herein include: frequency-shift keying (FSK); phase-shift keying (PSK); amplitude-shift keying (ASK); on-off keying (OOK); quadrature phase-shift keying (QPSK); offset quadrature phase-shift keying (OQPSK); minimum-shift keying (MSK); n -state quadrature amplitude modulation (n -QAM, i.e., 4-QAM, 16-QAM, 64-QAM, etc.); binary phase-shift keying (BPSK); multiple-state phase-shift keying (MPSK); multiple-state frequency-shift keying (MFSK); FM chirp modulation, pulse-time modulation, and many others.

Additionally, the capsule electronic chip 21 can include a radio-frequency synthesizer incorporated within the RF transmitter 15, which would permit precise digital selection of a number of frequencies in the band of interest. These ISM frequency bands in which RF devices are typically employed generally do not require licensing to operate so long as certain power and spectral-emission specifications are maintained. These bands are from 902-928 MHz, 2400-2483.5 MHz, 5150-5250 MHz, 5250-5350 MHz and 5725-5825 MHz. Additionally, other bands in the very-high frequency (VHF), ultra-high frequency (UHF), and microwave frequency (> 1 GHz) ranges can be used, and still others are currently proposed for medical equipment use and/or computer-networking use (typically above 5 GHz). Unfortunately, severe interference from television broadcast transmitters has been experienced with conventional RF medical telemetry devices when operated at some of these frequencies. Spread-spectrum systems such as those employed in the disclosed invention will eliminate these highly undesirable interference problems in both hospital/clinical and home settings. Furthermore, properly implemented spread-spectrum RF devices will dramatically reduce the likelihood of causing potentially dangerous interference to existing nearby sensitive medical electronic devices and systems.

Another major benefit of spread-spectrum modulation for the disclosed embodiment of the invention is its ability to reject

most levels of multi-path interference which can acutely and adversely limit the data quality in conventional narrow-band data-modulation schemes. To overcome this possible limitation, the preferred form of the disclosed invention utilizes direct-sequence spread-spectrum (DSSS), which can markedly reduce almost all errors caused by multi-path reflections, since the corresponding differential time delays due to the aforementioned multi-path reflections are typically greater than the DSSS chipping-sequence interval and are therefore ignored in the demodulation process. In addition, and preferably, the disclosed device can simultaneously employ time-, frequency-, and code-division multiplexing to achieve extremely effective channel separation for multiple-sensor applications.

Besides DSSS, other means of spread-spectrum spreading code techniques currently known in the art include time- and frequency-hopping modulation. Time-hopping (TH) refers to changing the timing of the bursts or pulses of streaming data so that it will transmitted in a pseudo-random fashion. Frequency-hopping (FH) permits the ability to "hop" or change the carrier frequency of the RF transmission in accord with pseudo-random p-n codes. It is extremely useful in real-world settings to employ combinations of these modulations; e.g., DSSS/FH, DSSS/TH (or more commonly denoted, *DS/FH* and *DS/TH*) to much more effectively counteract interference and multipath effects and simultaneously provide greater flexibility in configuring multi-sensor and/or multi-user scenarios in clinical settings.

The use of highly robust spread-spectrum RF techniques for data transmission also permits the monitoring receiver 44 to take the form of a portable pocket, pager, or belt-worn unit which could accompany the patient in routine day-to-day activities such as school, travel, shopping, etc. away from the clinical environment. Emergency data and alarms could then be automatically relayed via cellular networks, modems, or the like, for remote medical analysis, while key patient data is simultaneously archived and stored for detailed post-analysis.

The spread-spectrum RF system can also, via its substantial immunity to multi-path effects (caused for example by patient motion or environmental changes), facilitate the use of extremely high RF transmission frequencies. Thus, frequencies well above 1 GHz, by virtue of their short wavelengths (centimeters or less), will enable the development of very compact, yet reasonably efficient antenna structures within the tiny envelopes useful for unobtrusive micro-miniature implantable monitoring and/or treatment devices. At these very short RF signal wavelengths, spread-spectrum transmission can effectively compensate for sharp drop-out nulls caused by even minor head motions and provide error-free data transmission in even highly noisy, interference-prone signal-propagation conditions. The spread-spectrum RF transmitter also can be implemented to function ultrasonically to increase its efficiency.

Furthermore, by combining the use of multiple implanted sensors with available networking technologies, the implants can be used as a networked monitoring system.

Finally, it will be understood that the preferred embodiment has been disclosed by way of example, and that other modifications may occur to those skilled in the art without departing from the scope and spirit of the appended claims.

CLAIMS

What is claimed is:

5 1. An apparatus for monitoring intra-cranial cerebral spinal fluid pressure in a subject, said apparatus comprising

a sensor for sensing intracranial pressure;
control means for collecting data from said sensor

10 corresponding to sensed intracranial pressure;

a spread-spectrum transmitter;

means for communicating said data from said control
means to said transmitter;

15 a power source for powering said sensor and said
control means.

2. The apparatus of Claim 1 wherein said sensor is a
pressure transducer comprising a deflectable membrane having
one side of the membrane monitoring a reference pressure
20 condition and the opposite side of the membrane coupled to a
chamber of a fluid-handling system.

25 3. The apparatus of Claim 1 wherein said sensor
comprises one or more pressure transducers in combination.

4. The apparatus of Claim 1 wherein said spread-
spectrum transmitter is a radio-frequency transmitter that
operates in one or more frequency ranges of 902 - 928 MHz,
2450 - 2483.5 MHz, 5150 - 5250 MHz, 5250 - 5350 MHz, and
30 5725 - 5825 MHz.

5 5. The apparatus of Claim 1 wherein said spread-spectrum transmitter is a radio-frequency transmitter that operates at frequency of approximately 915 MHz.

6. The apparatus of Claim 1 wherein said spread-spectrum transmitter is an ultrasonic transmitter.

10 7. The apparatus of Claim 1 wherein said power source is one or more batteries of the type selected from the group consisting of lithium, nickel-cadmium, and a self-contained radioactive material.

15 8. The apparatus of Claim 1 wherein said power source is a capacitive element.

9. The apparatus of Claim 1 wherein said power source receives inductive power from an inductive power source which operates at a frequency less than 100 kHz.

20 10. The apparatus of Claim 1 wherein said power source receives inductive power from an inductive power source which operates at a frequency greater than 1 MHz.

25 11. The apparatus of Claim 1 wherein said power source receives inductive power from an inductive power source which operates at a frequency range of 100 kHz to 1 MHz.

12. The apparatus of Claim 1 wherein said data is transmitted to an external receiver by generation of a spreading-through spread-spectrum modulation, wherein said spread-spectrum modulation comprises, alone or in combination, direct-sequence modulation, frequency-hopping modulation, and time-hopping modulation.

13. The apparatus of Claim 2 wherein said fluid-handling system is controlled by a signal received from an external source.

14. The apparatus of Claim 1 further comprising an audible or visual alarm signal.

15. The apparatus of Claim 1 further comprising a receiving means for receiving control commands from an external source.

16. A monitoring apparatus in a subject, said apparatus comprising:

a sensor for sensing a physiological parameter;
control means for collecting data from said sensor
corresponding to a sensed physiological parameter;
a spread-spectrum transmitter;
means for communicating said data from said control
means to said transmitter;
a power source for powering said sensor and said
control means.

17. The apparatus of Claim 16 wherein said sensor monitors cerebral spinal fluid flow through thermal-mass flow.

18. The apparatus of Claim 16 wherein said sensor monitors cerebral spinal fluid flow through inertial-drag flow.

5 19. The apparatus of Claim 16 wherein said sensor is selected from the group consisting of: acoustic, piezoresistive, biochemical, electrochemical, electrical and conductive.

10 20. The apparatus of Claim 16 wherein said spread-spectrum transmitter is a radio frequency transmitter that operates in one or more frequency ranges of 902 - 928 MHz, 2450 - 2483.5 MHz, 5150 - 5250 MHz, 5250 - 5350 MHz, and 5725 - 5825 MHz.

15 21. The apparatus of Claim 16 wherein said spread-spectrum transmitter is a radio frequency transmitter that operates at a frequency of approximately 915 MHz.

20 22. The apparatus of Claim 16 wherein said spread-spectrum transmitter is an ultrasonic transmitter.

25 23. The apparatus of Claim 16 wherein said power source is one or more batteries of the type selected from the group consisting of lithium, nickel-cadmium, and a self-contained radioactive material.

24. The apparatus of Claim 16 wherein said power source is a capacitive element.

25. The apparatus of Claim 16 wherein said power source receives inductive power from an inductive power source which operates at a frequency less than 100 kHz.

5 26. The apparatus of Claim 16 wherein said power source receives inductive power from an inductive power source which operates at a frequency greater than 1 MHz.

10 27. The apparatus of Claim 16 wherein said power source receives inductive power from an inductive power source which operates at a frequency range of 100 kHz to 1 MHz.

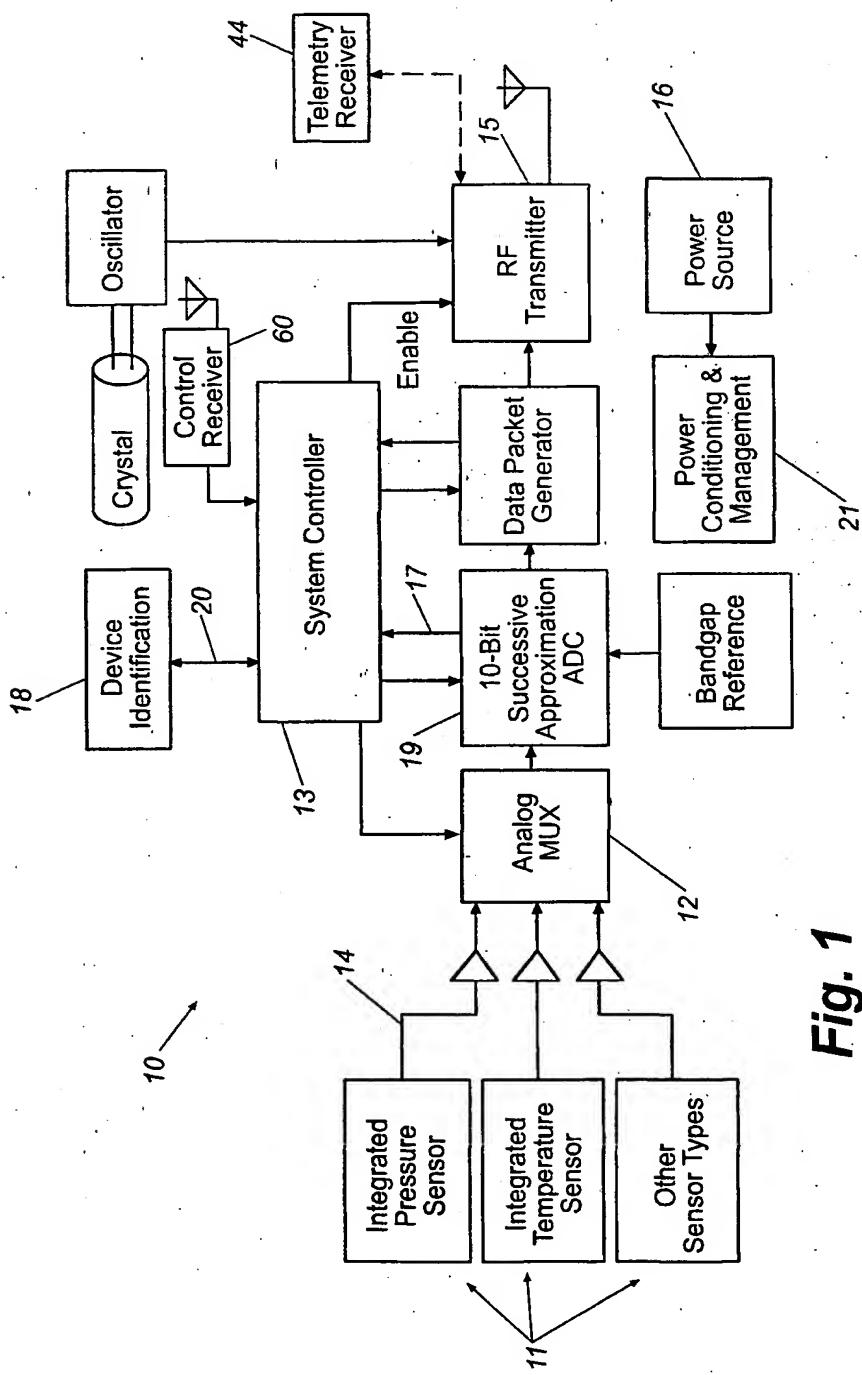
15 28. The apparatus of Claim 16 wherein said data is transmitted to an external receiver through spread-spectrum modulation, wherein said spread-spectrum modulation comprises, alone or in combination, direct-sequence modulation, frequency-hopping modulation, and time-hopping modulation.

20 29. The apparatus of Claim 16 capable of producing an audible or visual alarm signal.

25 30. The apparatus of Claim 16 used in combination, in one or more subjects, said combination transmitting data through multiple-access spread-spectrum modulation comprising code-division, frequency-division, and time-division multiplexing.

31. The apparatus of Claim 30, wherein said multiple-access-spread-spectrum modulation comprises frequency-shift keying, phase-shift keying, amplitude-shift keying, on-off keying, quadrature phase-shift keying, offset quadrature phase-shift keying, minimum-shift keying, n -state quadrature amplitude modulation, binary phase-shift keying, multiple-state phase-shift keying, multiple-state frequency-shift keying, frequency-modulation chirp modulation, and pulse-time modulation.
- 5
32. The apparatus of Claims 16 further comprising receiving means for receiving control commands from an external source.
- 10

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*Fig. 1*

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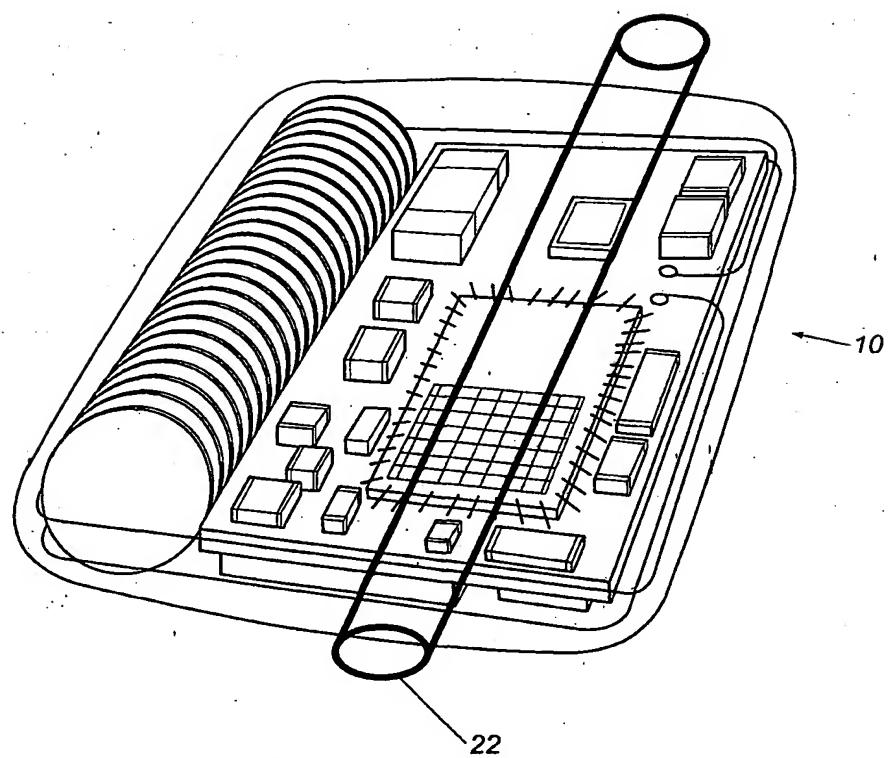


Fig. 2

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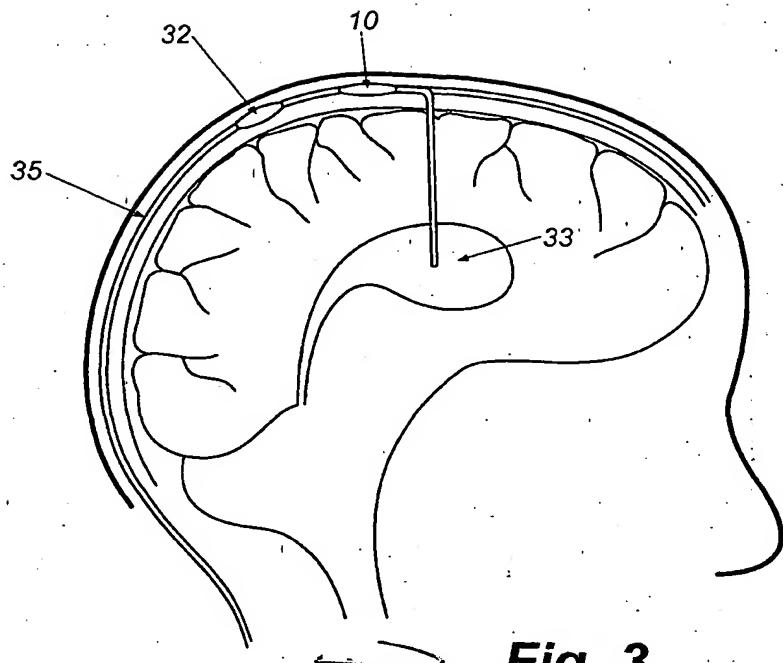


Fig. 3

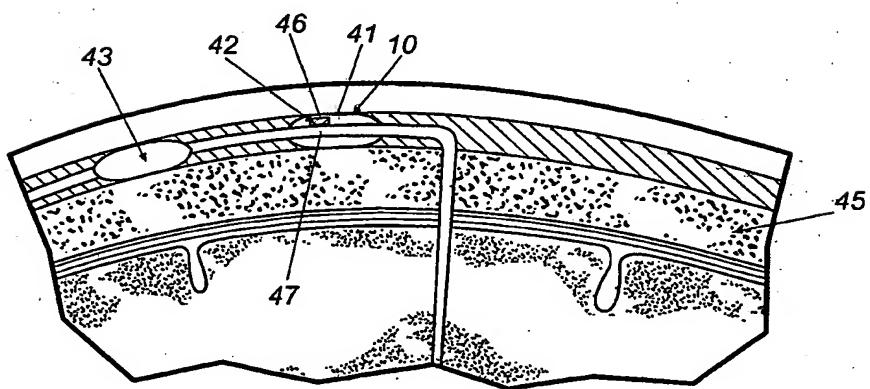


Fig. 4

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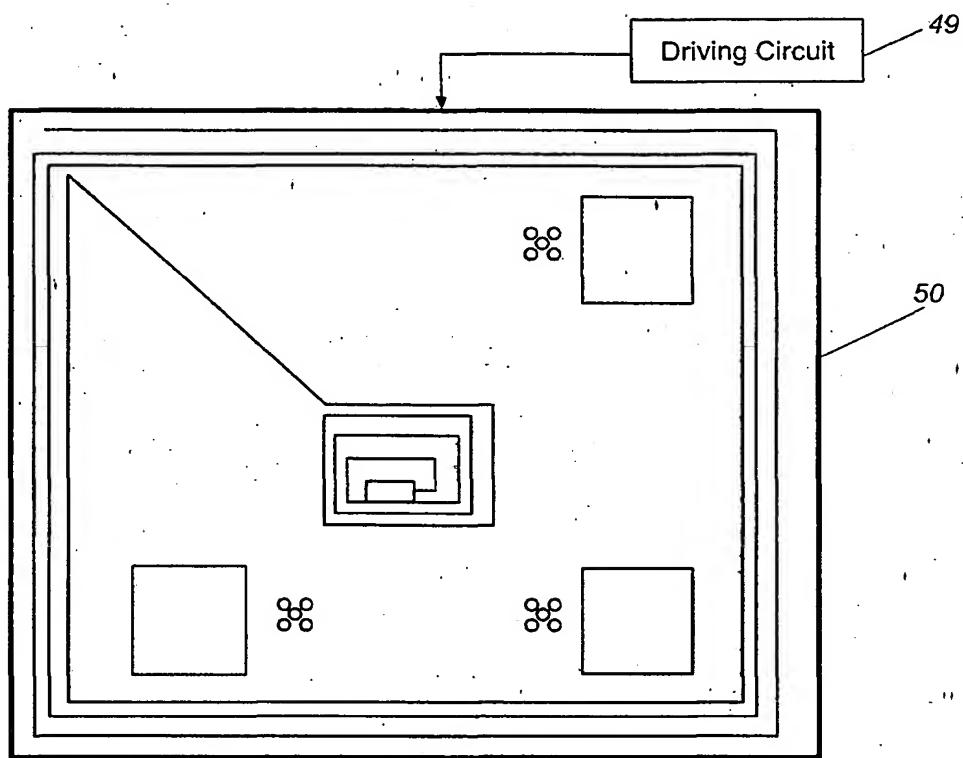
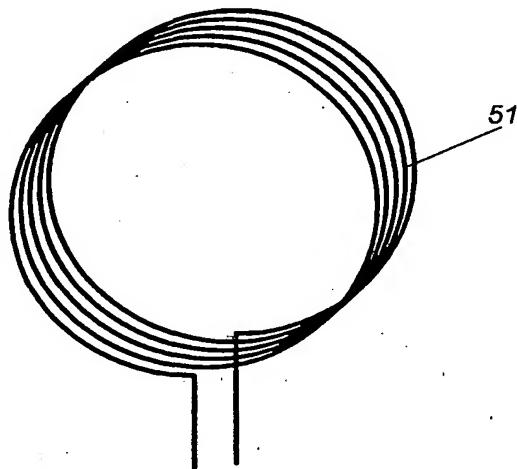


Fig. 5

Fig. 6



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/26168

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/03 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, COMPENDEX, INSPEC

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Further documents are listed in the continuation of box C.

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Date of the actual completion of the International search

10 January 2001

Date of mailing of the International search report

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Knüpling, M

INTERNATIONAL SEARCH REPORT

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PCT/US 00/26168

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International Application No
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